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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,426	11/03/2003	Lauren D. Johnson	047255-5003-US	6494
9629	7590	02/09/2006	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP			ROBINSON, KEITH O NEAL	
1111 PENNSYLVANIA AVENUE NW			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20004			1638	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,426

Applicant(s)

JOHNSON ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>November 14, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The cancellation of claims 1-31 and the addition of new claims 32-36, filed November 14, 2005, have been received and entered in full.

Claims 32-36 are under examination.

Response to Arguments

2. The objection of claims 5, 17, 19 and 30, filed in the previous Office Action mailed May 12, 2005, is moot due to Applicant's cancellation of claims in the 'Amendments to the Claims', filed November 14, 2005.

The 35 U.S.C. § 112, second paragraph rejection of claim 4, filed in the previous Office Action mailed May 12, 2005, is moot due to Applicant's cancellation of claims 1-31 in the 'Amendments to the Claims', filed November 14, 2005.

The 35 U.S.C. § 112, first paragraph rejection of claims 1-21 and 30, pertaining to lack of written description, filed in the previous Office Action mailed May 12, 2005, is moot due to Applicant's cancellation of claims 1-31 in the 'Amendments to the Claims', filed November 14, 2005.

The 35 U.S.C. § 112, first paragraph rejection of claims 1-21 and 30, pertaining to lack of enablement, filed in the previous Office Action mailed May 12, 2005, is moot due to Applicant's cancellation of claims 1-31 in the 'Amendments to the Claims', filed November 14, 2005.

The 35 U.S.C. § 102 rejection of claims 1-21 and 30, filed in the previous Office Action mailed May 12, 2005, is moot due to Applicant's cancellation of claims 1-31 in the 'Amendments to the Claims', filed November 14, 2005.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "sufficient tannins" in claim 34 is a relative term which renders the claim indefinite. The term "sufficient tannins" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant argues that because the 'Weston' variety is commercially available, one of ordinary skill in the art would be fully apprised of the scope of the invention (see page 5, last paragraph of 'Remarks' filed November 14, 2005).

This is not persuasive. The specification does not particularly point out what is considered “sufficient tannins” as compared to the ‘Weston’ variety. There is no measurable standard in terms of tannin levels. Table 4 of the specification shows an average score of varieties, but there is no indication of the tannin levels of the varieties (see page 27).

Claim Rejections - 35 USC § 112, first paragraph – Written Description

6. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 states, “wherein at least 25% of plants” and claim 33 states, “comprising a selection intensity of at least about 15%”. There is no support in the instant specification for these claims. Page 27, Table 4 and page 29, Table 5 of the specification lists percentages of plants with a staining score of 3 or more and none of the listed plants have “at least 25% of plants” or “a selection intensity of at least about 15%” and therefore, the claims constitute NEW MATTER.

7. Claims 32-36 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

Applicant argues that the present application allows a person of skill in the art to identify higher tannin plants (see page 6, 3rd paragraph to page 7, end of 2nd paragraph of 'Remarks' filed November 14, 2005).

This is not persuasive. The Examiner maintains the rejections of the previous Office Action mailed May 12, 2005 as pertaining to claims 1-21 and 30 for new claims 32-36 (see pages 4-6). The new claims are still broadly drawn to any alfalfa variety having detectable tannin levels. As stated in the previous Office Action, there is no written description of the genus of alfalfa plants having detectable levels of tannins.

Applicant argues that claim 34 states that the improved bloat safety is conferred by the plant tannins thus the relevant physiological characteristics of the plant are described (see page 7, 1st paragraph of 'Remarks' filed November 14, 2005).

This is not persuasive. The specification fails to adequately describe the broad genus of alfalfa varieties having sufficient tannins compared to the 'Weston' variety in terms of their genetic, morphological and/or physiological characteristics. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from

its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Claim Rejections - 35 USC § 112, first paragraph – Enablement

8. Claims 32-36 are rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement.

Applicant argues the instant application allows a person of ordinary skill in the art to produce a variety having increased tannins in the plant by selecting plants in the population which have the higher levels of tannin as parents (see page 8, 1st full paragraph of 'Remarks' filed November 14, 2005).

This is not persuasive. The new claims are drawn to an alfalfa variety, not a method of making alfalfa varieties. There is no guidance provided in the specification for the broad genus of alfalfa varieties scoring 3 or higher for leaf tannins using the DMACA-HCL regarding the genetic, morphological, and/or physiological characteristics. The Examiner maintains the rejection as set forth in the previous Office Action mailed May 12, 2005 for claims 1-21 and 30 for new claims 32-36.

Applicant argues that the instant specification provides evidence that the tannin expression is heritable (see page 8, 1st full paragraph of 'Remarks' filed November 14, 2005).

This is not persuasive. The heritability of the trait does not enable the claimed invention, an alfalfa variety having increased tannin levels. As stated previously, there is no guidance regarding the claimed invention, thus one of skill in the art would not know

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how to make and/or use the invention as it is broadly claimed. One skill in the art would not know how to distinguish the claimed invention from other alfalfa varieties that may possess similar traits. Applicant states, "having identified those plants with higher tannin levels, conventional breeding techniques can be applied to produce new varieties with improved tannins" (see page 8, 1st paragraph of 'Remarks' filed November 14, 2005).

Though it is possible to produce new varieties with improved tannin levels, this fact does not provide guidance for the claimed invention, which is an alfalfa variety having increased tannin levels. Without guidance regarding the genetic, morphological and/or physiological composition of the claimed invention one of skill in the art would not know make and/or use the claimed invention without undue trial and error experimentation.

Applicant argues that the specification describes that Table 3 summarizes the plants in the different crossing groups that resulted in cycle 1 seed and that these are the parents used to produce an alfalfa variety having increased tannin levels (see page 8, 2nd paragraph).

This is not persuasive. Though the Examiner agrees that Table 3 does lists the parents used in making an alfalfa variety having increased tannin levels, the Examiner maintains the rejection of the previous Office Action mailed May 12, 2005 wherein it was stated that this lists is merely a list of arbitrary numerical names of parent plants (see page 9, 2nd paragraph). Furthermore, there are parents on the list that are half-sibs, wherein there is no guidance regarding their derivation, as well as unknown parents that are from unknown sources. Therefore, it would require a person of skill in the art undue trial and error experimentation to make and/or use the claimed invention.

Applicant argues that selecting for alfalfa plants having increased tannin levels is not unpredictable (see page 9, 1st and 2nd paragraphs).

This is not persuasive. In the previous Office Action the Examiner pointed out three references to unpredictability. Two of these were in Applicant's specification which stated that temperature can play a role in the detection of tannin levels (see page 12, lines 7-8) and that age of the leaf can make it difficult to determine if an alfalfa plant has a detectable level of tannins (see page 13, lines 3-7). Applicant's assertion that these statements would allow one of skill in the art to avoid any difficulties that these factors may cause does not provide evidence to overcome the Examiner's assertion of unpredictability. The third reference to unpredictability was Bula et al, which taught that, repeated sexual propagation of an alfalfa synthetic may lead to changes in cultivar characteristics such that subsequent generations would no longer be similar to the original release (see pages 10-11 of the previous Office Action mailed May 12, 2005). Applicant has not provided any evidence to overcome the Examiner's art rejection.

Claim Rejections - 35 USC § 102

9. Claims 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Coulman et al (Can. J. Plant Sci. 80(3): 487-491, 2000). The claims read on an undisclosed alfalfa variety having increased tannin levels wherein said variety consists of at least 25% of plants having a score 3 or higher when grown under certain conditions in the field or greenhouse.

Applicant argues that Coulman et al uses selection of low rate of initial digestion as a way of trying to improve bloat safety and that they do not show any development of an alfalfa variety with improved tannin levels.

This is not persuasive. Coulman et al show that a bloat-reduced cultivar was developed in three phases: 1) pre-breeding, 2) selection and 3) evaluation (see pages 488-490). In addition, Coulman et al produced a bloat-reduced cultivar, namely alfalfa cultivar AC Grazeland (formerly named LIRD-4) (see page 490, 'RELEASE'). The specification discloses that alfalfa with increased tannins will help reduce the risk of bloat in animals (see page 4, line 29 to page 5, line 2); thus the alfalfa plants disclosed by Coulman et al would inherently possess high tannin levels. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lees (Plant Polyphenols, pp. 915-934, 1992). The claims read on an undisclosed alfalfa variety having increased tannin levels wherein said variety consists of at least 25% of plants having a score 3 or higher when grown under certain conditions in the field or greenhouse.

Lees teaches alfalfa plants having levels of tannin in their leaves while in culture (see page 929, 3rd paragraph).

Though Lees does not teach alfalfa plants having levels of tannin in their leaves under field and greenhouse conditions, it would have been *prima facie* obvious for one

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of ordinary skill in the art to modify the teachings of Lees to produce an alfalfa variety having increased tannin levels under certain field and green house conditions.

One of ordinary skill in the art would have been motivated to produce such an alfalfa variety because Lees teaches the desirability of increasing tannin content in alfalfa varieties (see page 929, 2nd paragraph of Lees).

In addition, one of ordinary skill in the art would have reasonable expectations of success based on the success of Lees in producing an alfalfa variety having increased tannin levels in culture (see page 929, 3rd paragraph).

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

February 1, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

